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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Application Number: 08/819,669

Filing Date: March 17, 1997

Appellant(s): BOON-FALLEUR ET AL.

Norman D. Hanson

For Appellant

EXAMINER'S ANSWER

This is in response to the Revised Appeal Brief, filed 02/12/2008, appealing from the Non-Final Office Action, mailed 02/26/2007 and the Advisory Actions, mailed 10/23/2007 and 12/27/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the Brief.

(2) Related Appeals and Interferences

It is acknowledged that the instant application was appealed previously on 06/07/2006 and that the Board of Patent Appeals REVERSED the Examiner, and remanded for further proceedings not related to the rejection at issue herein and that a copy of the Board's decision is presented in appellant's Related Proceedings Appendix.

The examiner is not aware of any other related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the Brief is correct.

This appeal involves claims 183-191.

Claims 1-182 have been canceled previously.

(4) Status of Amendments After Final

Appellant's statement of the status of amendments after final rejection contained in the Brief is correct.

(5) Summary of Claimed Subject Matter

While the basis of the summary of claimed subject matter contained in the Brief is correct, it is noted that the instant and issued claims of U.S. Patent No. 5,843,448 both encompass overlapping MAGE tumor rejection antigen precursors encompassing some variability in the structure of said tumor rejection antigen precursors, wherein the tumor rejection antigen precursors are encoded by nucleic acids, the complementary of which hybridizes to SEQ ID NO: 8 (see instant claims) or have a molecular weight of about 34.3 - 46 kilodaltons (see claims of U.S. Patent No. 5,843,448) (or see SEQ ID NO: 1 and Example 5 of U.S. Patent No. 5,843,448).

Further, it is noted that the instant claims do not recite MAGE-1, -2, -3, -4, -5 -6, -7. -8. -9, -10 nor -11, as described by appellant.

(6) Grounds of Rejection to be Reviewed on Appeal

Appellant's statement of the grounds of rejection to be reviewed on appeal is correct, except for the following.

Appellant has filed a Terminal Disclaimer on 12/12/2006 in the instant application over U.S. Patent No. 5,843,448.

Given applicant's Remarks, filed 09/18/2007, concerning that:

"With respect to common ownership, a statement of such cannot be made, because the ownership of U.S Patent No. 5,843,448 is joint, whereas the ownership of the current application resides with one party, Ludwig Institute for Cancer Research. The patent and application do not stand as prior art to each other, as each claims precisely the same priority";

the following has been noted.

In accordance with MPEP 804,

a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Here, the terminal disclaimer is not enforceable since the U.S. Patent and the instant application are not commonly owned.

Given appellant's Remarks, filed 09/18/2007 indicating that the U.S. Patent and the instant USSN are not commonly owned,

appellant was invited to consider filing a Petition to Expunge according MPEP 724.05 in order to expunge the Terminal Disclaimer previously filed 12/12/2006.

Appellant has not filed such a Petition.

However, as far as the Office is concerned currently,

the instant application and U.S. Patent No. 5,843,448 are commonly owned, given the filing of the terminal disclaimer over U.S. Patent No. 5,843,448 in the instant USSN 08/819,669.

Further, it is not the policy of the Office to declare interferences when the applications are commonly owned. See MPEP 804.03.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the Brief is correct.

(8) Evidence Relied Upon

A) Chen et al., U.S. Patent No. 5,843,448.

B) Terminal disclaimer, filed 12/12/2006 in USSN 08/819,669 over U.S. Patent No. 5,843,448.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Rejection under 35 U.S.C. § 102(f) or, in the alternative, under 35 U.S.C. 102(f)/103(a) because the applicants did not invent the claimed subject matter.

Claims 183-191 stand rejected under 35 U.S.C. § 102(f) or, in the alternative, under 35 U.S.C. 102(f)/103(a) because the applicants did not invent the claimed subject matter essentially for the reasons of record.

It is noted that SEQ ID NO: 8 of the instant USSN 08/819,669 is the same sequence as SEQ ID NO: 1 disclosed in Example 5 of U.S. Patent No. 5,843,448 (e.g., see Example 5 on columns 7-8 of U.S. Patent No. 5,843,448).

The patented claims of U.S. Patent No. 5,843,448 are drawn to MAGE-1 tumor rejection antigen precursor proteins and immunogenic compositions, which anticipate the instant MAGE tumor rejection antigen precursor proteins and compositions thereof. Further, it has been well known for decades by the ordinary artisan that vaccines and immunogenic compositions often comprise an adjuvant to increase the immunogenicity of the immunogenic or vaccine composition of interest.

(10) Response to Argument

Appellant's arguments have been fully considered but have not been found convincing essentially for the reasons of record.

For clarity and convenience, the following sets forth the independent claim of each of U.S. Patent No. 5,843,448 and the instant application USSN 08/819,669.

U.S. Patent No. 5,843,448

Claim 1. An isolated MAGE-1 tumor rejection antigen precursor which is either (i) a glycoprotein having a molecular weight of about 46 kilodaltons as determined by SDS-PAGE, or is (ii) a recombinantly produced protein having a molecular weight of about 34.3 kilodaltons as determined by SDS-PAGE, wherein said MAGE-1 tumor rejection antigen precursor comprises an epitope to which monoclonal antibody MA454, produced by hybridoma cell line ATCC 11540 binds.

USSN 08/819,669

Claim 183. An isolated, MAGE tumor rejection antigen precursor protein, wherein said protein is encoded by a nucleic acid molecule, the complementary sequence of which hybridizes to SEQ ID NO: 8 at 0.1xSSC, 0.1% SDS, wherein said tumor rejection antigen precursor is obtainable from melanoma cells.

As noted above, SEQ ID NO: 8 of the instant USSN 08/819,669 is the same sequence as SEQ ID NO: 1 disclosed in Example 5 of U.S. Patent No. 5,843,448 (e.g., see Example 5 on columns 7-8 of U.S. Patent No. 5,843,448, particularly column 8, paragraph 2).

In response to appellant's assertions concerning the case law interpreting 35 U.S.C. 102(f), the 102(f)/103(a) rejection is deemed appropriate and not a misreading of the claims nor a misinterpretation of the law.

With respect to appellant's finding of no distinction in 35 U.S.C. § 102(f) between patents and publications,

appellant is reminded that each claim of a U.S. Patent is presumed valid by U.S. courts unless proven otherwise. See 35 U.S.C. 282.

With respect to appellant's assertions that "since '448 enjoys a presumption of validity, it must be deemed to claim something not disclosed in '774 and since '774 has been held by the Examiner to be essentially identical to the subject application, '448 and the current application contain distinct and different disclosures;

appellant is reminded that each case is decided upon its own facts.

Also, it is well settled that whether similar claims have been allowed to others is immaterial. See In re Giolito, 188 USPQ 645 (CCPA 1976) and Ex parte Balzarini, 21 USPQ2d 1892, 1897 (BPAI 1991).

In addition, the following is noted for the record with respect to differences between SEQ ID NO: 8 of the instant application and related U.S. Patent No. 5,342,774 and with SEQ ID NO: 1 of U.S. Patent No. 5,843,448.

Appellant ignores that USSN 07/807,043, issued on 08/30/1994 as U.S. Patent No. 5,342,774 with an incorrect sequence.

In turn, U.S. Patent No. 5,342,774 was subject to Reissue USSN 08/590,097, now U.S. Patent No. RE40089, to correct the sequence and the sequence was not corrected until 12/27/200.

U.S. Patent No. 5,843,448, filed as USSN 05/560,024, issued on 12/01/1998 prior to the correction of the sequence in U.S. Patent No. 5,342,774 and the instant USSN 08/819,669 (sequence corrected in June/July 2000).

Also, note that U.S. Patent No. 5,342,774 was directed to nucleic acids, while the instant application is directed towards protein, and was restricted accordingly.

As indicated previously, appellant's apparent assertions that the inventions must be the same, implying that the claims must exactly the same scope, for a proper rejection under 102(f) is not consistent with legal precedent or guidance from the MPEP.

Where it can be shown that an applicant derived an invention from another, a rejection under 35 USC 102(f) is proper. See MPEP 706.02(g) and MPEP 2137.

Prior art under 35 USC 102(f) may be available under 35 USC 103.

See OddzOn Products, Inc. v. Just Toys, Inc., 43 USPQ2d 1641, 1644 (Fed. Cir. 1997)(35 U.S.C. "102(f) is a prior art provision for purposes of § 103"); Dale Electronics v. R.C.L. Electronics, 180 USPQ 225, 227 (1st. Cir. 1973); and Ex parte Andresen, 212 USPQ 100, 102 (Bd. App. 1981).

See MPEP 2004 and MPEP 706.02(l).

Further, it is noted that derivation is key to a rejection under 35 USC 102(f) and that derivation addresses originality (i.e. who invented the subject matter).

See MPEP 2137.

Also, for conception of specific compounds, one must have a mental picture of the structure or of other characteristics that distinguish it from the prior art.

See Board of Education ex rel board of Trustees of Florida State University v American Bioscience Inc., 67 USPQ2d 1252 (Fed Cir 2003).

Also, see MPEP 2137.01 and 2138.04.

Here, while the recitation of the instant claims do not recite MAGE-1 per se,

the instant claims recite a MAGE tumor rejection tumor antigen precursor encoded by the nucleic acid molecule, the complementary sequence of which hybridizes to SEQ ID NO: 8.

SEQ ID NO: 8 of instant USSN 08/819,669 is specifically drawn to MAGE-1.

While the recitation of the issued claims 1-3 in U.S. Patent No. 5,843,448 does not recite a SEQ ID NO. per se,

the issued claims of in U.S. Patent No. 5,843,448 are drawn to MAGE-1 tumor rejection antigen precursors and SEQ ID NO: 1 disclosed in Example 5 in U.S. Patent No. 5,843,448 encoding MAGE-1 tumor rejection antigen precursor is the same sequence as SEQ ID NO: 8 of instant USSN 08/819,669.

While it is noted that the instant claims are not limited to tumor rejection antigen precursors comprising / consisting of SEQ ID NO: 8 only;

it is noted that the issued claims of U.S. Patent No. 5,843,448 are not limited to a single species either.

Further, the instant claims do not recite any particular MAGE, such as MAGE-1 through MAGE-11, as described in the SUMMARY OF THE CLAIMED SUBJECT MATTER on pages 7-9 of the Brief.

Therefore, while the instant claims have some breadth,

the claims of U.S. Patent No. 5,843,448 also have some breadth and, in turn, anticipate or render obvious the instant claims.

While the scope of the instant and issued claims may differ,

both sets of claims are clearly drawn to or based upon the same or nearly the same reference sequence encoding tumor rejection antigen precursors, namely SEQ ID NO: 8 in the instant USSN 08/819,669 or SEQ ID NO: 1 in U.S. Patent No. 5,843,448.

It is the base or reference sequence structure encoding tumor rejection antigen precursors, namely SEQ ID NO: 8 in the instant USSN 08/819,669 or the structural limitations comprising SEQ ID NO: 1 in U.S. Patent No. 5,843,448, that are the key identifying characteristics that distinguishes the instant / issued claims from the prior art.

Given the base structural characteristics (e.g., sequence, MAGE-1) common to both the instant and patented claims, the instant and patented claims anticipate or render obvious one another.

With respect to the anticipation / obviousness of instant and issued claims over one another, the instant and issued claims both encompass overlapping MAGE tumor rejection antigen precursors encompassing some variability in the structure of said tumor rejection antigen precursors, wherein the in tumor rejection antigen precursors are encoded by nucleic acids, the complementary of which hybridizes to SEQ ID NO: 8 (see instant claims) or have a molecular weight of about 34.3 - 46 kilodaltons (see claims of U.S. Patent No. 5,843,448) (or see SEQ ID NO: 1 and Example 5 of U.S. Patent No. 5,843,448).

With respect to appellant's assertions that "recombinant MAGE-1 is described as being different from the molecule as being isolated via non-recombinant means and that '448 Patent provides no disclosure on the isolation of MAGE-1 via non-recombination means, clearly evidencing a species of invention, i.e., recombinant MAGE-1, which is not the same invention as is claimed herein";

appellant is reminded that the claim 1 of U.S. Patent No. 5,843,448 recites the following.

> An isolated MAGE-1 tumor rejection antigen precursor which is either (i) a glycoprotein having a molecular weight of about 46 kilodaltons as determined by SDS-PAGE, or is (ii) a recombinantly produced protein having a molecular weight of about 34.3 kilodaltons as determined by SDS-PAGE, wherein said MAGE-1 tumor rejection antigen precursor comprises an epitope to which monoclonal antibody MA454, produced by hybridoma cell line ATCC 11540 binds.

In contrast to appellant's assertions, claim 1 of U.S. Patent No. 5,843,448 recites both non-recombinant ((i)) as well as recombinant ((ii)) MAGE-1 tumor rejection antigen precursors.

With respect to asserted differences between non-recombinant and recombinant proteins, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) and MPEP 2113.

Also, note that claims 1-3 of U.S. Patent No. 5,843,448 do not recite a SEQ ID NO.

Further, appellant has filed a terminal disclaimer in the instant USSN 08/819,669 over U.S. Patent No. 5,843,448, indicative of appellant's acknowledgement of the inherency and/or obviousness between the instant and issued claims.

Further with respect to the ambiguity of the inventorship, the record in the instant application clearly indicates that the instant inventorship was responsible for isolating and identifying instant SEQ ID NO: 8 as encoding MAGE tumor rejection antigen precursors (e.g., see Declarations submitted 07/09/1998, 06/30/2000, 07/10/2000 by the instant inventorship to correct SEQ ID NO: 8. in USSN 08/819,669).

Therefore, the record of the instant application creates an ambiguity as to the inventorship of MAGE-1, as claimed in U.S. Patent No. 5,843,448 and relied upon herein in USSN 08/819,669.

Appellant appears to ignore that the instant application USSN 08/819,669 contains a terminal disclaimer over U.S. Patent No. 5,843,448 which states that it will be enforceable only so long as they are commonly owned (see Terminal Disclaimer filed 12/12/2006 in USSN 08/819,669).

However, appellant has taken the position that they are not commonly owned as follows.

"With respect to common ownership, a statement of such cannot be made, because the ownership of U.S Patent No. 5,843,448 is joint, whereas the ownership of the current application resides with one party, Ludwig Institute for Cancer Research. The patent and application do not stand as prior art to each other, as each claims precisely the same priority."

See the Remarks on page 3 of Amendment filed 09/18/2007 in the instant USSN 08/819,699.

It appears that appellant's Terminal Disclaimer and position that the instant application and the U.S. Patent No. 5,843,448 are not commonly owned would render the instant application and any issuing patent unenforceable.

Appellant has not filed a petition to the Office to withdraw / expunge the terminal disclaimer.

Therefore the way the record stands as follows.

It appears that the instant application has an executed terminal disclaimer standing against the Remarks of counsel that "with respect to common ownership, a statement of such cannot be made, because the ownership of U.S. Patent No. 5,843,448 is joint, whereas the ownership of the current application resides with one party, Ludwig Institute for Cancer Research."

It is noted that the same person is making both statements.

As far as the Office is concerned currently, the instant application and U.S. Patent No. 5,843,448 are commonly owned, given the filing of the terminal disclaimer in the instant application.

Further, it is not the policy of the Office to declare interferences when the applications are commonly owned. See MPEP 804.03.

With respect to appellant's assertions concerning priority and inventorship in USSN 07/807,043, the instant USSN 08/819,669 and U.S. Patent No. 5,843,438; the following is noted.

Regardless of the priority claim in either USSN 07/807,043, USSN 08/819,669 or in U.S. Patent No. 5,843,438;

appellant acknowledges that the inventorship differs between the instant application and U.S. Patent No. 5,843,438 and

the claims of U.S. Patent No. 5,843,438 anticipates or renders obvious the instant claims.

Regardless of the complete unity of inventorship between the priority application and the instant application,

appellant acknowledges that the inventorship differs between the instant application and U.S. Patent No. 5,843,438 and the claims of U.S. Patent No. 5,843,438 anticipates or renders obvious the instant claims.

Regardless of the identity of the disclosure between the priority application and the instant application,

the claims of U.S. Patent No. 5,843,438 anticipates or renders obvious the instant claims.

With respect to the inventorship in U.S. Patent No. 5,843,448;

it is noted that the Petition to Correct Inventorship in U.S. Patent No. 5,843,448 (filed as USSN 08/560,024) was filed 02/28/2007 and granted 07/26/2007; which was over eight (8) years subsequent to the issue date for U.S. Patent No. 5,843,448 (issued 12/01/1998).

Prior to 2007, there was no inventor in common between U.S. Patent No. 5,843,448 and the instant USSN 08/819,669.

In conclusion, as pointed out previously and addressed herein,

given the presumption of validity of U.S. Patent No. 5,843,448,

the differences between inventorship between the instant application and U.S. Patent No. 5,843,448;

the filing of a Terminal Disclaimer in the instant application over U.S. Patent No. 5,843,448;

the statements of counsel that the instant application and U.S. Patent No. 5,843,448 were not commonly owned at the time the invention was made are in common between the instant USSN 08/819,669 and U.S. Patent No. 5,843,448, and

the Declarations submitted 07/09/1998, 06/30/2000, 07/10/2000 by the instant inventorship to correct SEQ ID NO: 8;

there is ambiguity as to who invented the claims drawn to MAGE tumor rejection antigen precursor proteins, including MAGE-1 or SEQ ID NO: 8 recited in the instant claims, forming the basis of the instant MAGE tumor rejection antigen precursor proteins.

Because of the ambiguity of the inventorship, appellant has failed to provide a satisfactory showing, which would lead to a reasonable conclusion that the instant listed inventorship are the sole inventors of the claimed invention.

Appellant's arguments have not been found persuasive.

(11) Related Proceedings Appendix.

A copy of the Board Decision identified in the Related Appeals and Interferences section of the Examiner's Answer has been provided in the Related Proceedings Appendix of appellant's Brief.

Again, it is noted that the Decision by the Board of Patent Appeals on 06/07/2006 is not related to the rejection at issue herein.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Phillip Gambel/
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April 23, 2008

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